

60. (New) A medical device comprising the tube of claim 41 connected to at least one other member.

61. (New) The medical device of claim 41, selected from the group consisting of a blood tube, an infusion tube, a catheter, and a balloon catheter.

62. (New) A circuit for extracorporeal circulation comprising the tube of claim 41.

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#### REMARKS

Claims 18-62 are active. Independent Claim 18 is directed to a two layer tube, and independent Claim 41 to a three layer tube. These claims find support in the original claims and in the specification, for instance, at pages 24-25 and 30-31. Support for the new sheer peel strength limitation and 180° peel strength limitation in these claims is found on page 15, lines 16-23, page 17, lines 1-7, and page 31, lines 9-13. Dependent Claims 19-37 and 42-59 track and find support in the original claims. Support for the medical devices of Claims 38-40 and 60-62 is found on page 19, lines 6-18. Accordingly, the Applicants do not believe that any new matter has been added.

The Applicants thank Examiner Bruenjes and SPE Pyon for their helpful comments regarding clarification of the claim language. It was suggested that further clarification of the elements of the invention may also help address some of the prior art concerns and possible limitations that would help further distinguish the present invention from the cited prior art were discussed. These limitations included the deletion of open claim language “comprising” from independent claims and direction of the claims to either a two or three layer tube, and limitation of the resins of the invention to resins which are stable at 121°C. Claims 18-62 have now been so amended. Favorable consideration is respectfully requested.

### DRAWINGS

The drawings were objected to on the basis that the figures were not properly labeled. Formal drawings are appended to this response, which number the figures consecutively using Arabic numerals, e.g., Fig. 1A, 1B and 1C; Fig. 2; and Fig. 3. Each figure, e.g., Fig. 1, 2 and 3 is depicted on a separate sheet. Accordingly, the Applicants respectfully request that these drawings be approved by the examiner.

### ABSTRACT

A revised abstract is appended to this response. This abstract is a single paragraph on a separate sheet and does not exceed 150 words. Approval of the substitute Abstract is respectfully requested.

### SPECIFICATION

The specification was objected to as not referring to the PCT and foreign priority document in the first paragraph. This objection is moot in view of the amendment to page 1 of the specification to include this information.

### Rejection—35 U.S.C. 112, second paragraph

Claims 1-17 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite. This rejection is moot in view of the cancellation of these claims.

### Rejection—35 U.S.C. 102

Claims 1-4, 13-15 and 17 were rejected under 35 U.S.C. 102(b) as being anticipated by Heilmann et al., U.S. Patent No. 5,928,744. This rejection is moot in view of the cancellation of these claims. It would not apply to the new claims, which are directed to

tubes consisting of 2 or three defined layers, which are formed of resins which are dimensionally stable at 121°C. The Heilmann tubes comprise a connection layer formed of a resin which is dimensionally unstable at 121°C during autoclave sterilization. This connection layer of the prior art tube is purposely employed so that the tube may be fused via the connection layer to another medical article, such as a medical bag or connector during autoclave sterilization at 121°C.

The tubes of the present invention differ from those of Heilmann as they do not comprise a dimensionally unstable connection layer. To emphasize this difference, independent Claims 18 and 41 require that the tube has a shear peel strength of less than 35 N, as measured on a stuck or adhered portion of the outermost layer of said tube after autoclave sterilization at 121°C for 20 minutes, and has a 180° peel strength of less than 10 N, as measured by the test method defined in JIS K6854 after autoclave sterilization at 121°C for 20 minutes.

Moreover, the invention as now claimed would not be obvious over Heilmann as there is no suggestion in this document for eliminating the dimensionally unstable resin layer. Accordingly, the Applicants respectfully request that the prior art rejections over Heilmann be withdrawn.

#### Rejection—35 U.S.C. 103

Claims 5-9 were rejected under 35 U.S.C. 103(a) as being unpatentable over Heilmann et al., U.S. Patent No. 5, 928,744, in view of Strassmann et al., U.S. Patent No. 6,127,009. This rejection is moot in view of the cancellation of these claims. It would not apply to the new claims for the reasons discussed above.

#### Rejection—35 U.S.C. 103

Claims 10-12 were rejected under 35 U.S.C. 103(a) as being unpatentable over Heilmann et al., U.S. Patent No. 5, 928,744, in view of Takeuchi et al., U.S. Patent No.

5,264,488. This rejection is moot in view of the cancellation of these claims. It would not apply to the new claims for the reasons discussed above.

Rejection—35 U.S.C. 103

Claim 16 was rejected under 35 U.S.C. 103(a) as being unpatentable over Heilmann et al., U.S. Patent No. 5, 928,744. This rejection is moot in view of the cancellation of these claims. It would not apply to the new claims for the reasons discussed above.

CONCLUSION

In view of the above amendments and remarks, the Applicants respectfully submit that this application is now in condition for allowance. Early notification to that effect is earnestly solicited.

Respectfully submitted,

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A handwritten signature in black ink, appearing to read "Thomas Cunningham". The signature is fluid and cursive, with a large initial "T" and a long horizontal stroke at the end.

Thomas M. Cunningham, Ph.D.  
Registration No. 45,394

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MARKED-UP AMENDMENT

IN THE SPECIFICATION

On page 1, line 4, of the specification, immediately after the Title, please insert the following:

--Cross-reference to Related Applications

This application is a national-stage filing under 35 U.S.C. §371 of PCT/JP00/06493, filed September 22, 2000. This application also claims priority under 35 U.S.C. §119 to Japanese application 2000-120270, filed April 21, 2000.—

Please replace the Abstract on page 38 of the specification, with the revised Abstract attached on a separate page to this response.

IN THE CLAIMS

Cancel Claims 1-17.

Add new Claims 18-62:

--18.-62. (New)—



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### ABSTRACT

A multi-layered tube composed of at least two layers, each formed from a different resin, e.g. resin (I) or resin (II). Resin (I) contains 5 to 40 mass% of a polypropylene resin and 95 to 60 mass% of at least one hydrogenated copolymer. Resin (II) contains 45 to 100 mass% of a polypropylene resin and 55 to 0 mass % of a hydrogenated copolymer. The multi-layered tubes may be used in the field of medicine and provide tubing which is excellent in transparency, flexibility and anti-kinking properties, and which is durable during sterilization procedures with high-pressure steam. The multilayer tubing may also be safely disposed of as it generates no toxic gases, such as dioxin, when incinerated. The multilayered tubing has excellent connectability and may be bonded to other tubing using hot solvent bonding or solvent adhesion. The multilayered tubing which is free from generation of any toxic gas when incinerated, and which is excellent in hot solvent bonding or solvent adhesion to other tube.

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